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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL J. THOMPSON, ELIO P. MARIANI,
R. SAUL LEVINSON, and HERBERT G. LUTHER

Appeal 2009-001973
Application 10/767,431
Technology Center 1600

Decided:¹ June 26, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1-27. We have jurisdiction under 35 U.S.C. § 6(b).

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

STATEMENT OF THE CASE

The claims are directed to a method of treating a vulvovaginal candidiasis. Claims 1 and 9 are representative of the claims on appeal, and read as follows:

1. A method for the local treatment of a vulvovaginal candidiasis, which comprises:

treating said vulvovaginal candidiasis condition caused by a species of *Candida* selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* by applying to the vaginal tissue of a human a formulation comprising:

about 35 to about 45% w/w sorbitol solution; about 3 to about 8% w/w propylene glycol; about 0.001 to about 1% w/w edetate disodium; about 5 to about 11% w/w mineral oil; about 0.5 to about 5% w/w polyglyceryl-3-oleate; about 0.5 to about 5% w/w glyceryl monoisostearate; about 0.001 to about 1% w/w microcrystalline wax; about 0.5 to about 2% w/w silicon dioxide; about 0.001 to about 1 % w/w methylparaben; about 0.001 to about 1% w/w propylparaben; about 25 to about 45% w/w water; and about 0.5 to about 5% w/w butoconazole nitrate; and wherein the treatment is a single dose treatment.

9. A method for the treatment of an unidentified vulvovaginal fungal condition, which comprises:

administration to said fungal condition a bioadhesive, single dose treatment formulation comprising from about 0.500 to about 5.000% w/w butoconazole nitrate; and

wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

The Examiner relies on the following evidence:

Riley, Jr.	US 5,266,329	Nov. 30, 1993
Chen	US 6,267,985 B1	Jul. 31, 2001

Stedman's Medical Dictionary, 24th Edition, Williams & Wilkins, 394 (1982).

William Droegemueller, M.D. et al., “Three-Day Treatment with Butoconazole Nitrate for Vulvovaginal Candidiasis,” 64(4) *Obstetrics & Gynecology*, 530-534 (Oct. 1984).

Dale Brown, M.D., et al., “Butoconazole Nitrate 2% for Vulvovaginal Candidiasis-New, Single-Dose Vaginal Cream Formulation vs. Seven Day Treatment with Miconazole Nitrate,” 44(11) *The Journal of Reproductive Medicine* 933-938 (Nov. 1999).

Sanjay Garg et al., “Compendium of Pharmaceutical Excipients for Vaginal Formulations,” *Pharmaceutical Technology* 14-24 (2001).

Appellants rely on the following evidence:

M.E. Lynch et al., “Comparative *in vitro* activity of antimycotic agents against pathogenic vaginal yeast isolates,” 32 *Journal of Medical and Veterinary Mycology*, 267-274 (1994).

Sobel JD. et al., “Treatment of Complicated Candida vaginitis: Comparison of single and sequential doses of fluconazole,” 185 (2) *Am J Obstet Gynecol* 363-9 (Aug. 2001) (Abstract Only).

Sobel JD., “Antimicrobial Resistance in Vulvovaginitis,” 3(6) *Curr Infect Dis Rep* 546-9 (Dec. 2001) (Abstract Only).

Moosa MY et al., “Non-albicans Candida infections in patients with hermatologic malignancies,” 17(2) *Semin Respir Infect* 91-8 (Jun. 2002) (Abstract Only).

Sobel JD., “Treatment of vaginal Candida infections,” 3(8) *Expert Opinion Pharmacother*, 1059-65 (Aug. 2002) (Abstract Only).

Paul Nyirjesy et al., “Vaginal *Candida parapsilosis*: Pathogen or bystander?,” 13(1) *Infectious Diseases in Obstetrics and Gynecology* 37-41 (March 2005).

The following grounds of rejection are before us for review:

Claims 9 and 24-27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Brown; and

Claims 1-27 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Riley, Brown, Garg, Droegemueller, and Chen.

We reverse the anticipation rejection, but affirm the obviousness rejection.

ISSUE (Anticipation)

The Examiner finds that claims 9 and 24-27 are anticipated by Brown.

Appellants contend that Brown does not anticipate a method for the treatment of an unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

Thus, the issue on appeal is: Have Appellants demonstrated that the Examiner erred in finding that Brown teaches a method for the treatment of an unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*?

FINDINGS OF FACT

FF1 According to the Specification, the “present invention is directed to methods of treatment of a nonspecified *Candida* species isolate using antimycotic delivery systems.” (Spec. 1.)

FF2 The Specification teaches that “[v]ulvovaginitis is a common disorder that can affect females of all ages” that “encompasses a variety of disorders characterized by inflammation that may be secondary to multiple causes, including infection, irritation, allergy, and systemic disease.” (*Id.* at 2.)

FF3 In women of childbearing age, the Specification teaches that vulvovaginitis is usually caused by bacterial vaginosis, *Trichomonas* species and/or *Candida* species (*id.*). The *Candida* species that most often causes vulvovaginitis is *Candida albicans*, but vulvovaginitis may also be caused by *Candida glabrata* or *Candida tropicalis* (*id.*).

FF4 The Specification exemplifies a preparation of a formulation according to the invention (*id.* at 19 and 21), but provides no data as to the *in vivo* clinical efficacy of the formulations.

FF5 The Examiner rejects claims 9 and 24-27 under 35 U.S.C. § 102(b) as being anticipated by Brown (Ans. 3).

FF6 The Examiner finds that Brown teaches “the use of a single dose cream formulation of 2% butoconazole nitrate for vulvovaginal candidiasis.” (*Id.*)

FF7 The Examiner finds further that Brown teaches of the 150 known species of *Candida*, nine are pathogenic in humans, *i.e.*, the *albicans*, *glabrata*, *tropicalis*, *pseudotropicalis*, *lusitaniae*, *crusei*, *rugosa*, *parapsilosis*, and *guilliermondi* species (*id.* at 3-4).

FF8 The Examiner finds further that Brown teaches that 10-20% of vulvovaginal candidiasis are not caused by *C. albicans*, thus “[s]imply because Brown [] did not test for the presence of other fungal species of *Candida*, does not mean that they were not present especially in light of the fact that 10-20% of the cases are caused by non-*albicans* *Candida* species.” (*Id.* at 9.)

FF9 Thus, the Examiner finds that treatment of other *Candida* species is inherent in the method of Brown (*id.*).

FF10 The objective of Brown is to “compare the safety and efficacy of a single vaginal dose of a butaconazole nitrate 2% bioadhesive, sustained release cream (butoconazole 1-BSR) with a seven-day schedule of micanazole nitrate vaginal cream 2%.” (Brown, Abstract.)

FF11 Brown found that “[b]utaconazole 1-BSR rapidly relieved the signs and symptoms of vulvovaginal candidiasis.” (*Id.*)

FF12 In the clinical study performed by Brown, patients were tested for the presence of *C. albicans*, and those with “negative initial fungal cultures were withdrawn from the study.” (*Id.* at 935, second column.) In addition, the microbiologic cure was measured by absence of *C. albicans* in fungal cultures (*id.* at 936, first column).

FF13 Brown does teach, however, that there are 150 known species of *Candida*, of which about nine are pathogenic in humans, including the *albicans*, *glabrata*, *tropicalis*, *psuedotropicalis*, *lusitaniae*, *crusei*, *rugosa*, *parapsilosis*, and *guilliermondi* (*id.* at 934, first column).

FF14 Brown notes that *C. albicans* is responsible for the development of vulvovaginal candididiasis in 80-92% of the cases, but that there has been an

increase in non-*C. albicans* vulvovaginal candidiasis, which is of concern (*id.*). Brown also notes that *C. glabrata* is the second most encountered species, and “is considered to be less susceptible to standard treatment.” (*Id.*)

FF15 Brown teaches that Butoconazole was chosen for the one dose-treatment because of “its highly acceptable safety profile and proven clinical efficacy,” and “its broad antifungal spectrum, consistently showing high activity against the most important eight non-*albicans* *Candida* species.” (*Id.* at 934, second column.)

FF16 Brown also notes that while “*in vitro* susceptibility cannot always be extrapolated into clinical results, *in vitro* tests predicted clinical failure of flucanazole and tercanazole with respect to *C. glabrata* and *Saccharomyces cerevisiae*.” (*Id.*)

PRINCIPLES OF LAW

“It is well settled that a claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference.” *Celeritas Techs. Ltd. v. Rockwell Int’l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

We note, however

Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In re Oelrich, 666 F.2d 578, 581 (CCPA 1981)(quoting *Hansgird v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)) (internal citations omitted).

ANALYSIS

Appellants argue that independent claims 9 and 24 are directed to a method of treating an unidentified vulvovaginal fungal condition, wherein the condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* (App. Br. 14). Brown, Appellants assert, does not teach treatment of those *Candida* species, but only *Candida albicans*, as the patients studied were strictly chosen on the basis of the presence of *C. albicans* (*id.* at 16-17). Thus, Appellants assert, “[n]owhere in Brown [] is it expressly or inherently taught that any one of the 101 patients tested positive for a condition caused by a species of *Candida* selected from the group consisting of *C. dubliniensis*, *C. tropicalis*, *C. glabrata*, *C. parapsilosis*, *C. krusei*, *C. lusitaniae* or that the same could be treated.” (*Id.* at 17.)

We find that Appellants have the better position. While we agree with the Examiner that there is a possibility that the sample patient population were infected with a second *Candida* species, such as *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*, inherency may not be established by probabilities or probabilities. Although Brown was aware of other pathogenic species of *Candida*, only those patients who tested positive for the *albicans* species were admitted to the study, and

microbiologic cure was measured by absence of the *albicans* species in fungal cultures.

CONCLUSION(S) OF LAW

We thus find that Appellants have demonstrated that the Examiner erred in finding that Brown teaches a method for the treatment of an unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*.

The rejection of claims 9 and 24-27 under 35 U.S.C. § 102(b) as being anticipated by Brown is therefore reversed.

ISSUE (Obviousness)

The Examiner concludes that claims 1-27 are rendered obvious by the combination of Riley, Brown, Garg, Droegemueller, and Chen.

Appellants contend that the combination as set forth by the Examiner does not teach or suggest a method for the treatment of an unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*; and that the Examiner used improper hindsight in combining the references.

Thus, the issue on appeal is: Have Appellants demonstrated that the Examiner erred in concluding that Riley, Brown, Garg, Droegemueller, and Chen, as combined, teach or suggest a method for the treatment of an

unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*; and/or that the Examiner erred in using improper hindsight in combining the references?

FINDINGS OF FACT

FF17 The Examiner rejects claims 1-27 under 35 U.S.C. § 103(a) as being obvious over the combination of Riley, Brown, Garg, Droegemueller, and Chen (Ans. 4-8).

FF18 The Examiner addresses each of the Graham factors in reaching the determination of obviousness (*id.*).

FF19 Specifically, as to the limitation at issue, the Examiner cites Riley for teaching “a vaginal fungal infection wherein the active antimicrobial agent is an imidazole agent.” (*Id.* at 6.)

FF20 The Examiner relies on Brown for its teachings as set forth in the anticipation rejection (*id.*).

FF21 The Examiner cites Garg for its teaching of pharmaceutical excipients for vaginal formulations (*id.*).

FF22 The Examiner cites Droegemueller for its teaching that “one dose of 2 % butoconazole nitrate vaginal cream results in a maximum plasma level 24 hours after dosing.” (*Id.*)

FF23 Chen is cited by the Examiner for teaching “improved delivery of therapeutic agents, including anti-fungal agents, such as butoconazole, in a composition comprising polyglyceryl 2-4 oleate.” (*Id.* at 7.)

FF24 The Examiner concludes that it would have been obvious to use the formulations as required by the claimed methods as Riley suggests the use of imadazole as the anti-fungal in the formulations, and Brown demonstrates the effectiveness of butaconazole administered as a single dose (*id.* at 7-8).

FF25 Appellants have submitted a number of Abstracts from Sobel, without submitting the underlying documents.

FF26 However, for example, one Abstract, Sobel (*Expert Opinion in Pharmacotherapy* 2002), states that “vaginitis due to *Candida glabrata* is associated with a high treatment failure rate,” and that “considerable limitations in available therapy exist in the effective management of complicated vaginitis.”

FF27 Lynch, relied upon by Appellants, looks at the *in vitro* activity of antimyotic agents against pathogenic vaginal yeast isolates (Lynch, Title).

FF28 Lynch found that butoconazole had a “consistently high level of activity . . . against virtually all isolates tested.” (Lynch, 273.)

FF29 Lynch acknowledged that “*in vitro* susceptibility cannot be extrapolated into predicting *in vivo* activity or clinical success,” but that “*in vitro* sensitivity tests performed on *C. glabrata* and *S. cerevisiae* were useful in predicting clinical failure with TER and FLU and moderate success with CLO.” (*Id.*)

FF30 Lynch further acknowledges the need “for further investigation of the role of BUTO [butoconazole] and ITRA in experimental and clinical vaginitis, especially when caused by non-*albicans* species.” (*Id.*)

FF31 Nyirjesy was published in March 2005, which was after the instant filing date of January 30, 2004, and thus is not evidence of the state of the art at the time of filing.

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

In *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court rejected a rigid application of a teaching-suggestion-motivation test in the obviousness determination. The Court emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. Thus, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Further,

[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR, 550 U.S. at 417. It is proper to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418. *See also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated technical success, it is likely the product not of innovation but of ordinary skill and common sense.” *Id.* at 421.

Moreover, obviousness is determined in from the context of a person of ordinary skill in the art at the time the invention was made. “[T]he level of skill in the art is a prism or lens through which a judge, jury, or the Board views the prior art and the claimed invention. This reference point prevents these factfinders from using their own insight or, worse yet, hindsight, to gauge obviousness.” *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001), (citation omitted). Therefore, the evidence of record must be viewed through the lens of a person of ordinary skill in the art with consideration of common knowledge and common sense. *Graham*, 383 U.S. at 17-18; *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006).

ANALYSIS

Appellants argue that the references as combined do not teach all of the elements of the claimed method. As to Riley, Appellants contend that

the patent teaches the use of the formulations in the treatment of *C. albicans*, but not a *Candida* selected from *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae* (App. Br. 26). Appellants argue, that as discussed with respect to the anticipation rejection, Brown does not remedy that deficiency, and nor does Grag, Droegmueller, or Chen (*id.* at 27-29).

Appellants argue further that the Examiner has engaged in impermissible hindsight in combining the references to arrive at the claimed method (App. Br. 22). Appellants assert that the “teachings of Brown [] as evidenced by the additional publications of J.D. Sobel, demonstrate that Brown [] were unaware of a viable method for effectively treating the non-*albicans Candida* species.” (*Id.* at 23.) According to Appellants, the attached Sobel abstracts “relate to treatment of the different *Candida* species using various active agents in order to determine efficacy,” demonstrating that “much remained unknown at the time Brown [] was written.” (*Id.*)

Appellants further rely on Lynch, which was cited by Brown, for its teaching that there have been few studies comparing the *in vitro* activity of azoles against non-*C. albicans* species, as well as the clinical outcome in animal models or patients, and for its teaching that more work needed to be done to investigate the role of azoles such as butaconazole in experimental and clinical vaginitis, especially when not caused by *C. albicans* (*id.* at 24). Appellants also rely on Nyirjesy, filed after the filing date of the instant application, for its teaching that it was unclear whether non-*C. albicans* species caused vulvovaginal symptoms (*id.* at 24-25). Thus, Appellants assert, in view of the above cited references, “a person of ordinary skill in

the art could only arrive at the presently pending subject matter by way of impermissible hindsight.” (*Id.* at 25.)

We conclude that the obviousness rejection stands on a different footing than the anticipation rejection. Although Brown does not specifically teach testing for any pathogenic *Candida* species other than *albicans*, Brown clearly teaches that other pathogenic *Candida* species were known to cause vulvovaginal candidiasis, including those claimed by Appellants, *i.e.*, *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*. Brown also teaches that that butoconazole was chosen for the one dose-treatment because of “its highly acceptable safety profile and proven clinical efficacy,” and “its broad antifungal spectrum, consistently showing high activity against the most important eight non-*albicans* *Candida* species.” (FF15.) Thus, Brown clearly suggests treating vulvovaginal candidiasis caused by non-*albicans* *Candida* species, such as those claimed in the instant methods, with a one-dose treatment of butoconazole.

We have considered the Sobel abstracts submitted by Appellants, and we do not find that they teach otherwise. For example, while Sobel (Expert Opinion in Pharmacotherapy 2002), states that “vaginitis due to *Candida glabrata* is associated with a high treatment failure rate,” and that “considerable limitations in available therapy exist in the effective management of complicated vaginitis” (FF26), the claims are not limited to the treatment of *C. glabrata*. In addition, Lynch, also cited by Appellants teaches that butoconazole had a consistently high level of activity against virtually all the *Candida* isolates tested. Although both Brown and Lynch

acknowledge that *in vitro* activity is not absolutely predictive of *in vivo* activity, all that is required is a reasonable expectation of success, not absolute predictability. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Moreover, both Brown and Lynch teach that *in vitro* tests predicted clinical failure of fluconazole and tercanazole with respect to *C. glabrata* and *Saccharomyces cerevisiae* (FF16, FF29). Given those teachings, along with Brown's success in treating *C. albicans* with a one-dose treatment of butoconazole, as well as both Brown's and Lynch's teaching that butacanazole has a high level of activity against *Candida* species other than *albicans*, we conclude that the ordinary artisan would have had a reasonable expectation of success of treating the *Candida* species of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*, with a one-dose treatment of butoconazole, as required by the instant method claims. Appellants' reliance on the teachings of Nyirjesy does not convince us otherwise, as that reference was published after the instant filing date, and obviousness is determined as of the filing date.

CONCLUSIONS OF LAW

We conclude that Appellants have not demonstrated that the Examiner erred in concluding that Riley, Brown, Garg, Droegemueller, and Chen, as combined, teach or suggest a method for the treatment of an unidentified vulvovaginal fungal condition wherein the unidentified vulvovaginal fungal condition is caused by a *Candida* species selected from the group consisting of *dubliniensis*, *tropicalis*, *glabrata*, *parapsilosis*, *krusei*, and *lusitaniae*; or

that the Examiner erred in using improper hindsight in combining the references.

We thus affirm the rejection of claims 1-27 under 35 U.S.C. § 103(a) as being obvious over the combination of Riley, Brown, Garg, Droegemueller, and Chen.

SUMMARY

The rejection of claims 9 and 24-27 under 35 U.S.C. § 102(b) as being anticipated by Brown is reversed; and

The rejection of claims 1-27 under 35 U.S.C. § 103(a) as being obvious over the combination of Riley, Brown, Garg, Droegemueller, and Chen, is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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